Introductions for the Marketed Unapproved Drugs Workshop
(in order of the workshop presentations)

Opening Remarks
Andrew C. von Eschenbach, MD – Commissioner
U.S. Food & Drug Administration

Dr. von Eschenbach was sworn in as the 20th Commissioner of the U.S. Food and Drug Administration on December 13, 2006. As the former Director of the National Cancer Institute at the National Institutes of Health, he is a nationally recognized urologic surgeon and oncologist. He has held several prominent positions at University of Texas, MD Anderson Cancer Treatment Center in Houston.

Dr. von Eschenbach has been a distinguished leader in the field of cancer research and progressive patient care for over 30 years. We are honored that his many accomplishments, expertise and vast experience have brought him here to head the FDA.

Welcome
Steven K. Galson, MD, MPH – Director
Center for Drug Evaluation & Research (CDER)

US Public Health Service, Rear Admiral (RADM) Steven Galson was named Director of the Center for Drug Evaluation and Research (CDER) in July, 2005. He provides leadership for the Center's broad national and international programs in pharmaceutical regulation. Dr. Galson joined FDA in April 2001 as the CDER Deputy Director after holding senior level positions at the Environmental Protection Agency, the Department of Energy where he was the Chief Medical Officer, and the Department of Health and Human Services.. Dr. Galson is an Internal medicine physician, Board Certified in Preventive Medicine & Public Health and Occupational Medicine.

Overview of Unapproved Universe: Legal & Medical

Deborah M. Autor, Esq. – Director
Office of Compliance

Deborah Autor is the Director of CDER's Office of Compliance. She has been with FDA since 2002 and previously served as Associate Director for Compliance Policy in the Office of Compliance. Before joining FDA, Ms. Autor was a Trial Attorney for seven years at the Office of Consumer Litigation of the Department of Justice, where she litigated civil and criminal cases on behalf of FDA. Before that, Ms. Autor was an attorney in private practice, where she specialized in counseling FDA-regulated companies. The Office of Compliance advances CDER's mission of assuring that safe and effective drugs are available to the American people by protecting Americans from unsafe and ineffective drugs.

Regulatory Options: OTC Monograph

Reynold Tan, PhD – Interdisciplinary Scientist
Office of Nonprescription Products

Dr. Tan received his Bachelor's Degree in Biochemistry from the University of Pennsylvania and a Ph.D in Biochemistry from the University of Maryland. Prior to coming to FDA, he worked for 5 years as a research chemist for Knoll Pharmaceutical Company. Dr. Tan has been an Interdisciplinary Scientist in the Office of Nonprescription Products at FDA since 2002.

Chemistry, Manufacturing, and Controls Requirements

Moheb Nasr, PhD – Director
Office of New Drug Quality Assessment

ONDQA is responsible for quality assessments of new drugs, pre and post marketing, regulated by CDER. Dr. Nasr serves as the FDA lead at the International Conference on Harmonization (ICH) Q8 Expert Working Group and is a member of FDA's Council on Pharmaceutical Quality. After a distinguished academic career, Dr. Nasr joined the FDA in 1990.

Regulatory Options: ANDA

Gary Buehler, RPH – Director
Office of Generic Drugs

Mr. Buehler is a pharmacist and was appointed Director of OGD in July of 2001, after serving as the Deputy Director of that office since 1999. Mr. Buehler has worked for FDA since 1986. Prior to joining the Office of Generic Drugs, he was a Senior Regulatory Project Manager in the Division of Cardio-Renal Drug Products.

Regulatory Options: NDA Process

Kim Colangelo – Associate Director of Regulatory Affairs
Office of New Drugs

Ms. Colangelo is responsible for providing guidance on regulatory, scientific, policy, and administrative matters in the Office of New Drugs, and serves as the leader for two teams of project managers providing regulatory support for initiatives within OND and the Center. She has worked for the FDA since 1996.

NDA/Demonstrating Product Efficacy

Robert Temple, MD – Director, Office of Medical Policy *and*
Acting Director, Office of Drug Evaluation I

The Office of Medical Policy is responsible for assessing quality of clinical trials and for regulation of industry promotional materials through the Division of Drug Marketing, Advertising, and Communication (DDMAC). ODE I is responsible for the regulation of cardio-renal, neuropharmacologic and psychopharmacologic products. Dr. Temple has been with FDA for 34 years and spent about a decade as final CDER sign-off on DESI drugs. He has a long standing interest in design of clinical trials and assessment of evidence.

NDA Demonstrating Product Safety

John K. Jenkins, MD – Director
Office of New Drugs

Dr. Jenkins is currently the Director of the Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration. Dr. Jenkins joined FDA as a medical officer in the Division of Oncology and Pulmonary Drug Products in 1992. He subsequently served as Pulmonary Medical Group Leader and Acting Division Director before being appointed as Director of the newly created Division of Pulmonary Drug Products in 1995. Dr. Jenkins

became the Director of the Office of Drug Evaluation II in 1999 and served in that position until he was appointed to his current position in January 2002. Dr. Jenkins is Board Certified in Internal Medicine and Pulmonary Diseases.

Robert Meyer, MD – Director, Office of Drug Evaluation II

Dr. Meyer has been the Director of Office of Drug Evaluation II since 2002. The ODE is responsible for the regulation of endocrine/metabolic, pulmonary, allergy, rheumatologic, analgesic and anesthetic products. He is involved in a number of Center and Agency level activities such as chairing the Agency's Risk Assessment Guidance working group and the Drug Safety Oversight Board. Dr. Meyer began his career with FDA in 1994.

David Jacobson-Kram, PhD – Associate Director of Pharmacology and Toxicology, Office of New Drugs

Dr. Jacobson-Kram joined the Office of New Drugs in 2003. Prior to FDA, he has worked in the private sector holding such positions as the Vice President of Toxicology and Laboratory Animal Health and serving on the faculties of the George Washington University medical school and the Johns Hopkins University Oncology Center. Throughout his career, Dr. Jacobson-Kram has published extensively on genetic and molecular toxicology.

Pediatric Research Equity Act

Lisa Mathis, MD – Associate Director
Pediatrics and Maternal Health Staff

The Pediatric and Maternal Health Staff function within CDER to consult on pediatric, pregnancy, and lactation issues in clinical protocols, study reports, and labeling. Dr. Mathis is a board certified, practicing pediatrician who joined the FDA as a medical reviewer in 2000.

Exclusivity

Kim Dettelbach
Office of the General Counsel

Ms. Dettelbach is an associate chief counsel in the Food and Drug division of the HHS Office of General Counsel. Her practice concentrates on issues relating to generic drugs and exclusivity, 505(b)(2) NDAs, orphan drugs, and pediatric drug development. She has been with FDA for 8 years.

User Fees & Waivers

Mike Jones – Special Assistant
Office of Regulatory Policy

Mike Jones is a pharmacist and has been at FDA for 17 years and with the User Fee program since 1993.

Role of the Unapproved Drugs Coordinator

Sally Loewke, MD – Assistant Director of Guidance & Policy
Unapproved Drugs Coordinator

Dr. Loewke is the Assistant Director for Guidance and Policy in the Office of New Drugs (OND) in the FDA's Center for Drug Evaluation and Research (CDER). In this position, Dr. Loewke works to ensure an efficient standardized review process within OND by aiding in the development and implementation of review policies and procedures. As part of her duties, Dr. Loewke also serves as the Unapproved Drugs coordinator. Dr. Loewke has been with the FDA since 1996.